

## REMARKS

### Status of the Claims

No claims are amended with this paper.

Now pending are claims 1, 4, 5, and 7-10.

### Rejections under 35 U.S.C. §103(a)

In the Office Action, claims 1, 5, 7, and 10 stand rejected as unpatentable over Patel et al. (U.S. Patent No. 5,340,572). This rejection is traversed.

According to the Office Action, Patel “[teaches] a topical gel composition containing medicaments . . . . Diclofenac is disclosed . . . . Ammonium chloride at 0.01 – 5% is specified . . . Sustained efficacy is disclosed.” Office Action at page 3. The Office Action concludes, “It would have been obvious . . . to make a composition comprising a gel including diclofenac and ammonium chloride to achieve the beneficial effect of sustained efficacy in view of Patel et al.” Applicants respectfully disagree.

As an initial matter, it must be pointed out that Patel is directed to ophthalmic formulations, not to percutaneously absorbable preparations as in the present claims.

In addition, although Patel mentions in passing the use of “diclofenac,” Applicants respectfully contend that Patel does not disclose the use of sodium diclofenac as recited in the present claims. It will be appreciated that diclofenac and sodium diclofenac are different and may have different properties; for example, the absorbability of the two materials in a percutaneously absorbable preparation is not the same.

Furthermore, while the Office Action refers to Patel at column 8, lines 19-38 as disclosing the use of “[a]mmonium chloride at 0.01-5%,” Applicants point out that the cited portion of Patel does not disclose the use of ammonium chloride as cited by the Examiner. The only mention of ammonium chloride in Patel is in a listing of buffers at

column 7, line 64 (where no amounts are provided). In fact, Patel, at column 8, lines 12-20, provides that:

Equivalent amounts of one or more salts made up of cations such as potassium, ammonium and the like and anions such as chloride, citrate, ascorbate, borate, phosphate, bicarbonate, sulfate, thiosulfate, bisulfite and the like, e.g., potassium chloride, sodium thiosulfate, sodium metabiosulfite, sodium bisulfite, ammonium sulfate, and the like can also be used in addition to or instead of sodium chloride to achieve osmolalities within the above-stated ranges.

Applicants submit that this generalized recitation of cations and anions, and certain specific salts other than ammonium chloride, does not constitute a disclosure of ammonium chloride. No other portion of column 8 of Patel discloses the use of ammonium chloride. The salts disclosed at the cited portion of Patel are used to provide a desired osmolality of the ophthalmic formulation. Applicants contend that such a disclosure is not relevant to the absorbability of sodium diclofenac, and is not relevant to the patentability of the present claims.

Still further, although the Office Action stated that it would have been obvious to make a composition comprising a gel including diclofenac and ammonium chloride to sustained efficacy in view of Patel et al., the composition of Patel provides sustained efficacy by remaining in gel form in the eye for an extended period. Applicants respectfully submit that this is also not relevant to the claimed percutaneously absorbable preparations.

For at least the foregoing reasons, Applicants contend that the pending claims are not rendered unpatentable by Patel et al.

In the Office Action, claims 1, 4, 5, and 7-10 stand rejected as unpatentable over Ledger et al. (U.S. Patent No. 5,120,545) in view of Inagi. This rejection is traversed.

According to the Office Action, Ledger “[teaches] a matrix for transdermal administration of a drug . . . Ammonium chloride is specified . . . Analgesic agents including ibuprofen are disclosed.” Office Action at pages 3-4. The Office Action concludes, “It would have been obvious . . . to make a matrix comprising an analgesic such as ibuprofen and ammonium chloride to achieve the beneficial effect of reducing sensitization.” The Office Action further states that

it would have been further obvious to use diclofenac as the analgesic and acrylic as an adhesive in the composition of Ledger et al. in view of the fact that the former is known in the art as equivalent to ibuprofen and the latter is known in the art as an adhesive in view of Inagi et al.

Office Action at page 4. Applicants do not agree.

As an initial matter, Applicants respectfully submit that Ledger does not disclose ibuprofen as stated in the Office Action. The portions of Ledger cited in the Office Action as disclosing “analgesic agents including ibuprofen” (column 4, lines 45 and 63) in fact mention “anti-inflammatory agents” (line 45) and “ketoprofen” (line 63). At lines 42-43, Ledger mentions “analgesic and analgesic combinations,” but Applicants have not found any mention of ibuprofen at all in Ledger.

Moreover, Ledger mentions ammonium chloride as a weak base to raise the pH within lysosomes, as an antigen processing-inhibiting agent. Applicants submit that this is not relevant to the presently-claimed percutaneously absorbable preparations. The disclosure of Ledger cannot render obvious the presently-claimed percutaneously absorbable preparation.

Furthermore, Inagi is directed to hydrophilic adhesive base materials having excellent mechanical strength and adhesion to skin. There would be no motivation to combine the teachings of Ledger (even if the teachings as were as described by the Examiner) with the teachings of Inagi to arrive at the presently-claimed percutaneously

absorbable preparations. Ledger and Inagi are directed to different objectives. Moreover, Applicants submit that there would be no reasonable expectation of success in making such a combination to arrive at the presently-claimed percutaneously absorbable preparations.

For at least the foregoing reasons, Applicants contend that the pending claims are not rendered unpatentable by Ledger or Inagi, alone or in combination.

Reconsideration and withdrawal of the rejections is proper and such action is requested.

#### Conclusion

For at least the foregoing reasons, Applicants request reconsideration of the application. Early and favorable action is requested.

Applicants request any extension of time necessary for consideration of this response. If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**, under Reference No. 56769 (71526), Customer No. 21874.

Respectfully submitted,

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